

REMARKS

Favorable reconsideration of applicants' pending claims is respectfully requested in view of the above amendments and following remarks. Claims 2-5, 10 and 16-27 are pending in the application, with claims 18, 19 and 20 being in independent format.

Independent claim 18 has been amended to recite, in part, an intracorporeal medical device including a rotatable torque tube and a sealing assembly, the sealing assembly comprising a housing including an infusion port and a liner that extends longitudinally less than the axial length of the torque tube in a distal direction from the infusion port, wherein the liner remains stationary with respect to the torque tube during rotation of the torque tube. Claim 18 has also been amended to correct a minor error in the language in the claim, namely to recite that the liner forms a flood space between the inner surface of the liner and the torque tube. Independent claim 19 has been amended to recite, in part, an aspirating catheter device comprising a torque tube, a liner surrounding the torque tube that extends longitudinally less than the axial length of the torque tube and terminates at an intersect area, and a catheter enclosing the torque tube and the liner, wherein the catheter extends distally beyond the intersect area with respect to an operator of the device and forms an aspiration lumen between the catheter and the liner. Independent claim 20 has been amended to recite, in part, a medical device comprising a rotatable torque tube, a liner surrounding the torque tube and forming a flood space extending longitudinally from a sealing assembly along at least a portion of the torque tube to a distal terminal end of the liner at an intersect area, and a catheter that forms an aspiration lumen between the catheter and liner and encloses the distal terminal end of the liner. Claims 21-27 have been amended to correct minor, non-substantive errors in the language of the claims.

Support for the above amendments may be found, for example, in paragraphs 0014, 0024, 0032, 0035 and 0044 of the specification, in Figure 3 and in claim 6, all as originally filed. It is urged that all of the above amendments are fully supported by the application as originally filed and that none of the amendments constitute new matter.

Claim Rejections under §102(b)

Claims 2-5, 10, 16-21, 26 and 27 stand finally rejected under 35 USC §102(b) as being anticipated by Keith et al., U.S. Patent 5,938,670. This rejection is respectfully traversed in view of the above amendments and the following remarks.

The devices and liquid seal assemblies described and claimed in this application are directed to sealing a rotating drive shaft without using a high tolerance bushing to provide a seal between an outer surface of the rotating drive and an opening to the outside environment. In the context of a medical device, such as an aspirating catheter that also provides liquid infusion to a site of intervention, any bushing or other component that the rotating drive shaft transits must have a very high tolerance in order to prevent leakage of air into the space and leakage of infusion liquids from the space. During high speed rotation of the drive shaft, significant friction may be generated at the interface of the bushing with the drive shaft, producing undesirable locally high temperatures. Moreover, conventional high tolerance bushings do not provide an adequate seal for drive shafts that are not solid, such as helical drive shafts that are commonly used in interventional catheter devices.

Applicants' solution to this sealing dilemma is to provide a liner surrounding the rotating drive shaft (or torque tube), and to immerse a flood space in the interior of the liner with liquid. The liquid environment surrounding the rotating drive shaft (torque tube) provides a seal from the outside environment that is frictionless and therefore does not produce heat during rotation of the drive shaft. The liquid seal also prevents loss of vacuum at the proximal end of the sealing assembly. The pressure within the flood space generally decreases along the length of the liner, and the dimensions of the liner (e.g., length and cross-sectional diameter) may be adjusted as desired to reduce the flow rate in the flood space to an appropriate level while providing a liquid seal. Liquid providing the seal may eventually exit the liner at a distal terminal end of the liner and may be aspirated back through an aspiration lumen. That is, the liquid flowing through the flood space and providing a friction-free seal for the rotating drive shaft may be collected and withdrawn through the aspiration system. The amended claims clarify that the liner remains stationary as the torque tube rotates freely with respect to the liner and that the liner and flood space extend for a portion of the length of the drive shaft less than the axial length of the drive shaft.

Keith et al. disclose an ablation system having an exchangeable drive/catheter system and incorporating both aspiration and infusion. The disclosure includes several different arrangements for infusion of cooling liquids. The drive shaft sheath 79, which the Examiner refers to as the "liner," is a conventional sheath that overlies the outer surface of the drive shaft and extends for substantially the entire length of the drive shaft to seal the drive shaft and prevent leakage of fluids from within the sheath.

The sealing assemblies of Applicants' claimed devices are not conventional infusion systems, although they may be used in conjunction with conventional infusion systems. Applicant's claimed devices incorporate a liner providing a flood space for creating a liquid seal around the rotatable torque tube during operation of the device. Amended independent claim 18 specifies that the liner surrounds the rotatable torque tube in the area of an infusion port and extends longitudinally less than the axial length of the torque tube in a distal direction from the infusion port, forming a flood space between the inner surface of the liner and the torque tube, whereby sealing liquid enters the flood space and prevents air from entering the space external to the torque tube during operation of the device.

Amended independent claim 19 similarly provides that the liner extends longitudinally less than the axial length of the torque tube and terminates distally at an intersect area. Claim 19 further specifies that a catheter encloses the torque tube and liner, and extends beyond the intersect area distally with respect to an operator of the device, forming an aspiration lumen between the catheter and the liner, whereby liquid drawn into the flood space during operation of the catheter exits the flood space at the intersect area and enters the aspiration lumen. Amended independent claim 20 similarly specifies a medical device incorporating a torque tube and a liner, wherein the liner forms a flood space that extends longitudinally along at least a portion of the torque tube to a distal terminal end of the liner at an intersect area. Claim 20 further recites that the device includes a catheter that encloses the distal terminal end of the liner and forms an aspiration lumen.

The Examiner asserts that the drive shaft sheath 79 of Keith et al. corresponds to the liner of the present claims. However, applicants note that Keith et al. state that "drive shaft sheath 79 extends from a position adjacent distal end of the bearing 56 to a position between the distal end of the catheter tube 70 and a proximal end of the ablating burr 18" (col. 12, lines 8-11). This is

illustrated in Fig. 4 of the reference. Thus, the catheter tube 70 of Keith et al. does not enclose the distal terminal end of the drive shaft sheath 79, as clearly recited in amended independent claims 19 and 20. Nor does the drive shaft sheath 79 of Keith et al. extend longitudinally for less than the length of the drive shaft, as recited in independent claim 18.

It is submitted that the disclosure of Keith et al. does not teach or suggest all the features of the presently pending claims and that the rejection of claims 2-5, 10, 16-21, 26 and 27 under 35 USC §102(b) may thus be properly withdrawn.

Claim Rejections under §103(a)

Claims 22 and 23 stand finally rejected under 35 USC §103(a) as being obvious over Keith et al. This rejection is respectfully traversed.

The Examiner states that Keith et al. fail to disclose a liner having the dimensions recited in claims 22 and 23, but asserts that it would have been obvious to one of skill in the art to optimize the dimensions. However, as discussed above, Keith et al. do not teach or suggest features of the present invention clearly recited in independent claims 18-20. It is therefore urged that the disclosure of Keith et al. would not have rendered the subject matter of dependent claims 22 and 23 obvious to one of skill in the art, and that the rejection of claims 22 and 23 under 35 USC §103(a) may be properly withdrawn.

Claims 24 and 25 stand finally rejected under 35 USC §103(a) as being obvious over Keith et al., in view of Milo (U.S. Patent 6,258,052) and Machold et al. (U.S. Patent 4,496,720). This rejection is respectfully traversed.

The teachings of Keith et al. are discussed above. Milo teaches that using a polyimide tube in conjunction with a coiled wire in a guidewire shaft increases pushability and column strength of the guidewire. Machold et al. teach the use of polyimide tubing have an inner lubricious lining of PTFE. Neither of these references overcome the deficiencies of Keith et al.

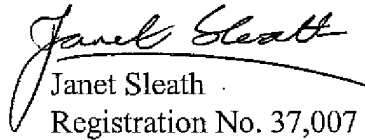
Applicants submit that one of these three references, taken either singly or in combination, teach or suggest the presently claimed subject matter, and that this rejection of claims 24 and 25 under 35 USC §103(a) may thus be properly withdrawn.

Conclusion

Every effort has been made to put the pending claims in condition for allowance. Early reconsideration and allowance of pending claims 2-5, 10 and 16-27 is respectfully requested.

The Examiner is invited to telephone the undersigned at 206.382.1191 if she has questions or if a discussion of the pending claims or the prior art references relied upon for rejection would be beneficial.

Respectfully submitted,


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